
MINUTES OF THE MEETING

**PRE BID MEETING OF TENDER FOR SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION
OF VIAL FILLING AND STOPPERING MACHINES
AT HLL BIOTECH LIMITED, CHENGALPATTU, CHENNAI**

DOCUMENT NO. : NPI-120310-EQP-S1-TD-01 dated 10th January, 2014

VENUE : HLL Biotech Limited, Chennai

DATE : 22.01.2014

PROJECT : Integrated Vaccines Complex, Chengalpattu

ATTENDEES : See attached list of attendees

ISSUED BY : CEO, HLL Biotech Ltd

ISSUED ON : 24th January 2014

Agenda	
1.	Pre-bid Meeting for Vial filling and stoppering machines at HBL, Chengalpattu

S. No.	Clarifications on queries																		
	Tender for Supply , Installation, commissioning and Validation of Vial filling and Stoppering machines at HLL Biotech limited, Chengalpattu .																		
A	Discussion on Tender Enquiry Document: NPI-120310-EQP-S1-TD-01																		
	Specific revision/ General Discussion Points																		
1.	The last date for the tender submission has been extended till 18th February 2014; 15:00 hrs and the tender opening will be on 18th February 2014; 15:30hrs																		
2.	AutoCAD Format of the room layouts is attached as annexure.																		
3.	Purchaser shall provide 100 vials and 3000 stoppers of each type to the qualified vendor for designing of the equipment.																		
4.	Purchaser shall provide required quantity of vials and stoppers of each type to the qualified vendor for conducting the FAT.																		
5.	Following are the timelines for supplying the filling and stoppering machines from the date of issuing of Letter Of Intent [LOI] / Letter Of Award[LOA] F1-VFS 01 -- 09 months F1-VFS 02 -- 10 Months F2-VFS 01 – 11 Months Installation, commissioning and validation: 2 months from the date of delivery at site.																		
6.	Vendor has asked for the clarification on transfer philosophy [URS annexure-3], Scope of the supply includes of one peristaltic pump to recirculate the vaccine between the manifold and buffer vessel and another peristaltic pump to transfer the vaccine from single use bag/mobile pressure vessel to the buffer vessel. Hence vendor to consider these 2 no.s peristaltic pump and buffer vessel in their scope of supply.																		
S. No.	Clarifications on URSS																		
B	URS: F1-VFS-02																		
6	Specific revision in the URS																		
	URS Point number and excerpt* / description of the specification *				Point modified as / Comment														
6.1	Point 2.0 Equipment operation requirements:																		
	Product No.	Vial size	Fill volume	Capacity	Stoppering														
	Product - 1	Customised	0.6 ml	200 Vials/min	Half stoppering														
	Product - 1	Customised	1.2 ml	200 Vials/min	Half stoppering														
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	Note: colour of the vial is Amber <u>Annexure 6 of the URS to be ignored.</u>																		

S. No.	Clarifications on queries																																																	
C	URS: F2-VFS-01																																																	
7	Specific revision in the URS	Point modified as / Comment																																																
7.1	<p>Point No: 4.1 Desired / suggested capacity The filling line should be suitable for line output of 200vial/min of 2R &6R vials respectively to produce filled and stoppered vials at the rate of:</p> <table border="1"> <tr> <td>2R</td> <td>200 vials/min with fill vol of 0.65ml</td> </tr> <tr> <td>6R</td> <td>200 vials/min with fill vol of 6.0ml</td> </tr> </table> <p>Vendor shall consider ISO 6R and 2R vials.</p>	2R	200 vials/min with fill vol of 0.65ml	6R	200 vials/min with fill vol of 6.0ml	<p>Point No: 4.1 Desired / suggested capacity The filling line should be suitable for line output of 200vials/min of 2R, 6R and minimum of 100 vials/min of Customised vials of product-2</p> <table border="1"> <thead> <tr> <th>Product No.</th> <th>Vial size</th> <th>Fill volume and capacity</th> </tr> </thead> <tbody> <tr> <td rowspan="2">Product-1</td> <td>2R</td> <td>200 vials/min with fill vol of 0.65ml</td> </tr> <tr> <td>6R</td> <td>200 vials/min with fill vol of 6.0ml</td> </tr> <tr> <td>Product-2</td> <td>Customized vial</td> <td>100 vials/min with fill vol of 11 ml</td> </tr> </tbody> </table> <p>Vendor shall consider ISO 2R, 6R and Customized vials. Vial Size of Product-2 is given below,</p> <table border="1"> <thead> <tr> <th colspan="3">15 mL Glass Vials (for use with 20 mm stoppers)</th> </tr> <tr> <th>S. No.</th> <th>Tests</th> <th>Specification</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Overflow capacity</td> <td>15.50 ± 0.50 mL</td> </tr> <tr> <td>2</td> <td>Mouth internal diameter</td> <td>12.60 ± 0.20 mm</td> </tr> <tr> <td>3</td> <td>Mouth external diameter</td> <td>19.60-20.10 mm</td> </tr> <tr> <td>4</td> <td>Body outer diameter</td> <td>24.0 ±0.2 mm</td> </tr> <tr> <td>5</td> <td>Body wall thickness</td> <td>1.00 ± 0.04 mm</td> </tr> <tr> <td>6</td> <td>Total height</td> <td>49.7±0.5 mm</td> </tr> <tr> <td>7</td> <td>Neck height</td> <td>9.0 ± 0.5 mm</td> </tr> <tr> <td>8</td> <td>Collar height</td> <td>3.9mm ± 0.2mm</td> </tr> <tr> <td>9</td> <td>Total weight</td> <td>10.0 ± 1.0 g</td> </tr> </tbody> </table>	Product No.	Vial size	Fill volume and capacity	Product-1	2R	200 vials/min with fill vol of 0.65ml	6R	200 vials/min with fill vol of 6.0ml	Product-2	Customized vial	100 vials/min with fill vol of 11 ml	15 mL Glass Vials (for use with 20 mm stoppers)			S. No.	Tests	Specification	1	Overflow capacity	15.50 ± 0.50 mL	2	Mouth internal diameter	12.60 ± 0.20 mm	3	Mouth external diameter	19.60-20.10 mm	4	Body outer diameter	24.0 ±0.2 mm	5	Body wall thickness	1.00 ± 0.04 mm	6	Total height	49.7±0.5 mm	7	Neck height	9.0 ± 0.5 mm	8	Collar height	3.9mm ± 0.2mm	9	Total weight	10.0 ± 1.0 g
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Some parties has send the queries through email , for which the specific answers are given below. All the vendors have to consider the clarification has given by HBL/NNE as applicable to all concerns

URS Page NO.	URS point	Queries by vendors through E- mail on URS - F2 – VFS 01	Clarification from HBL/ NNE
5	2.0 /1	Infeed on turntable is nevertheless possible see Point 3.1	Turntable required, as the line to be integrated with the De-Pyrogenation machine being procured separately.
7	3.1. a)	Infeed to double belt and not turntable, as 2R vials are considered as not stable and may topple down when using turntable. Turntable is nevertheless possible. Transport by screw, wheel and rake.	We are considering for maintaining flexibility and integration with the De-Pyrogenation and the Lyophilizer / Capping machine being procured separately.
7	3.1. c)	Buffer vessel of 3,5 L Specification Annexure 3 is missing	It is already hosted along with original tender.Vendors are requested to check it again.

7	3.1. d)	Specification Annexure 3 is missing	It is already hosted along with original tender.Vendors are requested to check it again.
7	3.1. e)	Vials out feed via out feed turntable	Synchronization between filling + stoppering machine and the sealing line of importance, accordingly, turntable has been provided.
7	3.2. a)	Turntable is not required	Same as above. (Synchronization)
7	3.2. b)	Turntable is not required	Same as above. (Synchronization)
8	4.1.	6R vials output of 11.000 /h.max.	6R vials output to be 200 vials / minute (12,000 vials / hr.)
9	6.2 A. d)	There is no infeed turntable! Infeed system see 3.1 a) with alarm system	The turntable at the feed of Vial Filling line shall be provided, shall have control to give alarm if the vial filling line is not functioning and the turntable is getting full.
9	6.2.B. b)	There is no vacuum necessary;venturi system by air pressure	Pressure of the air being utilized shall be monitored and controlled. For any reason, if the pressure drops, alarm shall be generated.
9	6.2. B. d)	Not applicable, because of rake transport this expulse any vial toppling	Look into the URS, requirement as defined above and provide the design accordingly.
10	6.4.	Differential Pressure :- Due to, that the LF system is not in the scope of supply; this item is not applicable	Item related / connected to the Vial filling line shall be covered in the Vial Line supplier's scope.
10	6.4.	Vacuum - Not applicable see item 6.2.B.b.)	The Vacuum if required for the Vial filling / Stoppering line shall be specified and system to be provided, if required for vendors design
11	6.6.8 c)	Mock up test is not applicable; because during the first day of FAT the position and machining of the glove ports will be done together with the user!	That's okay. However, it has to be jointly / together discussed and decided before finalizing.
11	6.6.8. d)	Not applicable, because LF system is not in the scope of supply.	The arrangement for Pressure measurement across the HEPA to be part of the frame system to be provided by the Vial Filling line supplier.
12	6.7.4.	No special Mock up; filling accuracy & Machine output is a basic element of the PQ at FAT time	Filling accuracy and machine output shall be one of the elements during FAT.
12	6.7.13. a)b)c)	Not applicable, because there is no infeed turntable!	As presented earlier (above), there shall be a turntable for synchronization between the de-pyrogenation tunnel and the filling line.
12	6.7.14	Will be done with frequency controlled drives.	Servo motor shall be preferred as against the Frequency controlled device.
12	6.7.15. b)	Capacity: 3,5 L	There will not be any change in the URS specification.
13	6.7.16. i)	There is no vacuum necessary venturi system by air pressure	The Vacuum if required for the Vial filling / Stoppering line shall be specified and system provided. i.e., if required.

URS Page NO.	URS point	Queries by vendors through E-mail on URS- F1-VFS-01	Clarification from HLL Biotech Limited/NNE
5	2.01 1	Infeed on turntable is nevertheless possible see Point 3.1	Turntable is required, as the line to be integrated with the De-Pyrogenation machine being procured separately.
5	2.01 7	Collection of the vials on outfeed turntable and outfeed tray	Turntable / similar system required to integrate the line with the Lyophilizer / sealing machine being procured separately.
7	3.1. a)	<i>Infeed to double belt and not turntable, as 2R vials are considered as not stable and may topple down when using turntable. Turntable is nevertheless possible. Transport by screw, wheel and rake.</i>	We are considering for maintaining flexibility and integration with the De-Pyrogenation and the Lyophilizer / sealing machine being procured separately.
7	3.1. c)	<i>Bulk / Mobile vessel will not be in scope of supply. Only the Buffer vessel of 3.5 L</i>	We require system for extended LAF to accommodate the Bulk / Mobile vessel (single use bag) under it.
7	3.1. d)	<i>Buffer vessel of 3.5 L. Specification Annexe 3 is missing!</i>	Buffer Vessel is defined in Annexure – 5. The same is uploaded in the website.
7	3.2 a)	Turntable is not required	For Synchronization between De-Pyrogenation tunnel and the filling line is required to be provided by vendor.
8	3.2 g)	Whether outfeed of vials are via outfeed turntable and tray	Cassetting Station Integration required for Vials to be collected into cassettes and transferred to Lyophilizer.
8	3.3 b)	This is in the scope of the producer of the Lyophilizer	Yes. However, the cassetting arrangement shall be in the scope of Vial Line Supplier. The Frame details shall be provided by the purchaser in coordination with the Lyophilizer supplier.
9	6.2 A. b)	Please clarify the oRABS system requirement	O RABS is required and shall be in the scope of Vial Line Supplier.
9	6.2 A. d)	There is no infeed turntable! Infeed system see 3.1a) with alarm system.	The turntable at the feed of Vial Filling line shall be provided shall have control to give alarm if the vial filling line is not functioning and the turntable is getting full.
9	6.2. B. b)	There is no vacuum necessary; venturi system by air pressure	Pressure of the air being utilized shall be monitored and controlled. For any reason, if the pressure drops, alarm shall be generated.
9	6.2. B.d)	Not applicable, because of rake transport this expulse any_ vial toppling	If not applicable, then it is good. Otherwise, this is required to be detected and corrected.
10	6.4.	Differential Pressure :- Due to, that the LF system is not in the scope of vendor; differential pressure is not applicable	Accepted
10	6.4.	Vacuum:-Not applicable see item 6.2.B.b.)	The Vacuum if required for the Vial filling / Stoppering line shall be specified and system to be provided, if required for vendors design

11	6.6.8 c)	Mock up test is not applicable; because during the first day of FAT the position and machining of the glove ports will be done together with the user!	That's okay. However, it has to be jointly / together discussed and decided before finalizing.
11	6.6.8 d)	Not applicable, because LF system is not in the scope of Vendor.	Accepted.
12	6.7.4.	No special Mock up; filling accuracy & Machine output is a basic element of the PQ at FAT time!	Filling accuracy and machine output shall be one of the elements during FAT.
12	6.7.14 a)b)c)	Not applicable, because there is no infeed turntable!	A turntable is required for synchronization between the de-pyrogenation tunnel and the filling line.
12	6.7.15	Whether the transport can be done with frequency controlled drives.	Servo motor is shall be preferred as against the Frequency controlled device.
12	6.7.16 a)	Whether the bulk vessel (40L) and peristaltic pump is in vendors scope	The bulk vessel is not in the scope of the filling line vendor. However, filling line supplier to provide the peristaltic pump for transfer of material from Bulk tank (bag) to the buffer vessel.
12	6.7.16 b)	Capacity: 3.5 L	There will not be any change in the URS specification.
13	6.7.17 i)	There is no vacuum necessary; venturi system by air pressure	The Vacuum if required for the Vial filling / Stoppering line shall be specified and system provided. i.e., if required.
14	6.7.21 a)	Whether the Outfeed can be via outfeed turntable and outfeed system	In-feed through turntable and out-feed through Cassetting station for lyophilization.
URS Page Nr.	URS point	Queries by vendors through E-mail on URS F1-VFS 02	Clarification from HLL Biotech Limited/NNE
5	2.0	URS Annexure-6 is missing	The same is not applicable as the vial specification is changed to ISO 4R vials in place of customized vials
5	2.0 11	Infeed on turntable is nevertheless possible see Point 3.1	Turntable is required, as the line to be integrated with the De-Pyrogenation machine being procured separately.
5	2.0 / 7	Collection of the vials on outfeed turntable and outfeed tray	Turntable / similar system required to integrate the line with the Lyophilizer / Capping machine being procured separately.
7	3.1. a)	Infeed to double belt and not turntable, as 2R vials are considered as not stable and may topple down when using turntable. Turntable is nevertheless possible. Transport by screw, wheel and rake.	We are considering for maintaining flexibility and integration with the De-Pyrogenation and the Lyophilizer / Capping machine being procured separately.

7	3.2 a)	Turntable is not required	For Synchronization between De-Pyrogenation tunnel and the filling line ,Turntable is required
7	3.2 b)	Turntable is not required	Same as above. (Synchronization)
7	3.2 f & g)	Vials out feed via out feed turntable and tray system	Cassetting Station Integration required for Vials to be collected into cassettes and transferred to Lyophilizer.
8	3.3 b)	This is in the scope of the producer of the lyophiliser	Yes. However, the cassetting arrangement shall be in the scope of Vial Line Supplier. The Frame details shall be provided by the purchaser in coordination with the Lyophilizer supplier.
8	6.2 A. b)	Please clarify the requirement of oRABS system	O RABS is required and shall be in the scope of Vial Line Supplier.
9	6.2 A. d)	There is no infeed turntable Infeed system see 3.1 a) with alarm system.	The turntable at the feed of Vial Filling line shall be provided shall have control to give alarm if the vial filling line is not functioning and the turntable is getting full.
9	6.2.B. b)	There is no vacuum necessary; venturi system by air pressure	Pressure of the air being utilized shall be monitored and controlled. For any reason, if the pressure drops, alarm shall be generated.
9	6.2. B.d)	Not applicable, because of rake transport this expulse any_ vial toppling!	If not applicable, then it is good. Otherwise, this is required to be detected and manually corrected.
10	6.4	Differential Pressure - Due to, that the LF system is not in the scope of vendor; this item is not applicable	Accepted.
10	6.4.	Vacuum is Not applicable see item 6.2.B.b.	The Vacuum if required for the Vial filling / Stoppering line shall be specified and system to be provided, if required for vendors design
11	6.6.8 c)	Mock up test is not applicable; because during the first day of FAT the position and machining of the glove ports will be done together with the user!	That's okay. However, it has to be jointly / together discussed and decided during FAT
11	6.6.8. d)	Not applicable, because LF stem is not in the scope of Vendor.	Accepted
11	6.7.4.	No special Mock up filling accuracy & Machine output is a basic element of the PQ at FAT time!	Filling accuracy and machine output shall be one of the elements during FAT.
12	6.7.1 4. a)b)c)	Not applicable, because there is no infeed turntable	There shall be a turntable for synchronization between the de-pyrogenation tunnel and the filling line.
12	6.7.15	Will be done with frequency controlled drives.	Servo motor shall be preferred as against the Frequency controlled device.

12	6.7.16 . a)	Whether the bulk vessel (40L) and peristaltic pump is in vendors scope	The bulk vessel is not in the scope of the filling line vendor. However, filling line supplier to provide the peristaltic pump for transfer of material from Bulk tank (bag) to the buffer vessel.
12	6.7.16 . b)	Whether Capacity of buffer vessel can be 3.5 L	There will not be any change in the URS specification.
13	6.7.17 . i)	There is no vacuum necessary; venturi system by air pressure	The Vacuum if required for the Vial filling / Stoppering line shall be specified and system to be provided.
14	6.7.20 . a)	Whether the Outfeed can be via outfeed turntable and outfeed system	In-feed through turntable and out-feed through Cassetting station for lyophilization.
14	6.7.20 . b)	Not applicable see item 6.7.20. a)	As applicable

The minutes of the pre bid meeting shall form a part of our tender no. **NPI/120310/EQP/S1/TD/01 dated 10th January, 2014.**

For HLL Biotech Limited

Chief Executive Officer

LIST OF ATTENDEES

Project : Integrated Vaccines Complex, Chengalpattu
 Date of Meeting : 22nd January 2014
 Venue : HBL, TICEL Biopark, Taramani, Chennai
 Subject : Pre Bid Meeting - supply, Installation, commissioning and validation of filling & stoppering machines at IVC.

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